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EXPEDITED REVIEW

Manual Thrombus-Aspiration Improves Myocardial Reperfusion

The Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus-Aspiration in Primary and Rescue Angioplasty (REMEDIA) Trial

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OBJECTIVES The aim of this study was to evaluate the use of a new manual thrombus-aspirating device in unselected patients with ST-segment elevation acute myocardial infarction (STEMI) undergoing urgent percutaneous coronary intervention (PCI).

BACKGROUND Failure to achieve myocardial reperfusion often occurs during PCI in patients with STEMI. The use of thrombus-aspirating devices might improve myocardial reperfusion by reducing distal embolization.

METHODS We prospectively randomized before coronary angiography 100 consecutive patients with STEMI to either standard PCI or PCI with manual thrombus-aspiration. Primary end points of the study were post-procedural rates of myocardial blush grade (MBG) ≥2 and ST-segment resolution (STR) ≥70%. Analyses were planned by intention to treat.

RESULTS Ninety-nine patients entered the analyses. The rates of post-procedural MBG ≥2 and STR ≥70% were, respectively, 68.0% and 44.9% in the thrombus-aspiration group compared with 58.0% and 36.7% in the standard PCI group: odds ratio (OR) 2.6 (95% confidence interval [CI] 1.2 to 5.9), p = 0.020, and 2.4 (95% CI 1.1 to 5.3), p = 0.034, respectively. Moreover, the rate of patients achieving both the angiographic and electrocardiographic (ECG) criteria of optimal reperfusion was significantly higher in the thrombus-aspiration group compared with standard PCI: 46.0% versus 24.5%, OR 2.6 (95% CI 1.1 to 6.2), p = 0.025. In multivariate analysis, randomization to thrombus-aspiration was a significant independent predictor of achievement of MBG ≥2 and STR ≥70% (p = 0.013).

CONCLUSIONS This prospective randomized study shows that manual thrombus-aspiration in unselected patients with STEMI undergoing primary or rescue PCI is clinically feasible and results in better angiographic and ECG myocardial reperfusion rates compared with those achieved by standard PCI. (J Am Coll Cardiol 2005;46:371–6) © 2005 by the American College of Cardiology Foundation

Early data from our group (1) and other groups (2,3) suggest that simple manual thrombus-aspirating devices might reduce the culprit coronary lesion's thrombus burden and facilitate myocardial reperfusion in selected patients. Thus, we have performed the present single-center, prospective randomized study to evaluate the possible benefit of manual thrombus-aspiration during percutaneous coronary intervention (PCI) in unselected, consecutive patients with ST-segment elevation acute myocardial infarction (STEMI).

METHODS

Study population and randomization. The study protocol was approved by the ethics committee of our institution. All patients within 12 h of onset of STEMI referred for primary or rescue PCI to our catheterization laboratory between January 2004 and November 2004 entered the study after obtaining written consent for the procedure. No angiographic exclusion criteria were adopted. After enrollment and before coronary angiography, patients were randomly assigned 1:1 to undergo either standard PCI or PCI with thrombus-aspiration according to a computer-generated random series of numbers.

Thrombus-aspirating device. The Diver CE (Invatec, Brescia, Italy) is a rapid-exchange, 6-F compatible, thrombus-aspirating catheter. It has a central aspiration lumen and a soft, flexible, 0.026-inch, non-traumatic tip with multiple holes (one large anterior and three smaller lateral ones) communicating with the central lumen. A 30-ml luer-lock syringe is connected to the proximal hub of the central lumen for thrombus-aspiration (1).

Percutaneous coronary intervention and medications. In patients randomized to standard PCI (standard PCI group),

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Abbreviations and Acronyms
CTFC = corrected TIMI frame count
MBG = myocardial blush grade
PCI = percutaneous coronary intervention
STEMI = ST-segment elevation acute myocardial infarction
STR = ST-segment resolution
TIMI = Thrombolysis In Myocardial Infarction

after crossing of the target lesion with the guidewire, direct stent implantation was attempted if judged possible by the operator, whereas in the remaining cases pre-dilation with an undersized balloon was used before stent implantation.

In patients randomized to manual thrombus-aspiration (thrombus-aspiration group), after placement of the guidewire, the Diver CE (Invatec) was slowly advanced in aspiration two to five times (depending on operator choice and on the angiographic result obtained) through the culprit lesion. Thereafter, the procedure was continued at the operator's discretion.

All patients were treated by heparin (initial weight-adjusted intravenous bolus then further boluses administered with the aim of obtaining an activated clotting time of 250 to 300 s in patients treated with abciximab and >300 s in the remaining subjects) and with double antiplatelet therapy with aspirin and clopidogrel (loading dose of 300 mg followed by 75 mg/day) for at least four weeks. Unless contraindicated, abciximab (0.25 mg/kg bolus plus infusion of 0.125 μg/kg/min for 12 h) was intravenously administered in all patients undergoing primary PCI, whereas in those with failed thrombolysis, abciximab use was left to the operator's discretion.

Clinical data collection, electrocardiogram, and laboratory data. Clinical data were prospectively collected on dedicated case report forms. Pre-intervention and post-

Table 1. Baseline Clinical and Angiographic Characteristics of the Study Population

	Thrombus-Aspiration (n = 50)	Standard PCI (n = 49)	p Value
Age (yrs) (mean ± SD)	61 ± 13	60 ± 13	0.76
Gender: males (%)/females (%)	45 (90.0%)/5 (10.0%)	38 (77.6%)/11 (22.4%)	0.09
Risk factors			
Smokers	31 (62.0%)	26 (53.1%)	0.37
Hypercholesterolemia	27 (54.0%)	17 (34.7)	0.06
Hypertension	31 (62.0%)	28 (57.1%)	0.62
Diabetes mellitus	11 (22.0%)	9 (18.4%)	0.65
Positive family history	15 (30.0%)	11 (22.4%)	0.96
Previous history of IHD	10 (20.0%)	10 (20.4%)	0.96
Pre-infarction angina	14 (28.0%)	16 (32.7%)	0.61
Anterior MI	20 (40.0%)	25 (51.0%)	0.27
Symptoms-to-angiography time (min)	274 ± 137	300 ± 202	0.28
Referred after failure of thrombolysis	16 (32.0%)	12 (24.5%)	0.41
Use of abciximab	34 (68.0%)	31 (63.3%)	0.53
Renal failure (creatinine ≥1.2 mg/dl)	6 (12.0%)	8 (16.3%)	0.53
Killip class III or IV	15 (30.0%)	14 (28.6%)	0.88
Cardiogenic shock	4 (8.0%)	5 (10.2%)	0.74
Arterial pressure (mm Hg)			
Systolic (mean ± SD)	129 ± 31	123 ± 33	0.40
Diastolic (mean ± SD)	77 ± 17	76 ± 17	0.74
Heart rate (beats/min) (mean ± SD)	71 ± 13	75 ± 19	0.17
Multivessel disease	17 (34.0%)	21 (42.9%)	0.36
LAD as culprit vessel	20 (40.0%)	25 (51.0%)	0.15
Culprit lesion with proximal location	26 (52.0%)	21 (42.9%)	0.27
Left ventricular ejection fraction*	46 ± 12	47 ± 11	0.36
Stenosis severity			
Occlusive (100%)	31 (62.0%)	30 (61.2%)	0.83
Sub-occlusive (90% to 99%)	18 (36.0%)	19 (38.8%)	
Pre-intervention TIMI flow grade			
0	32 (64.0%)	34 (69.4%)	
1	11 (22.0%)	10 (20.4%)	0.48
2	2 (4.0%)	3 (6.1%)	
3	5 (6.3%)	2 (4.1%)	
Thrombus score			
1	5 (10.0%)	4 (8.2%)	
2	6 (12.0%)	10 (20.4%)	0.72
3	10 (20.0%)	8 (16.3%)	
4	29 (58.0%)	27 (55.1%)	

*Evaluated by echocardiography within 48 h from admission.
IHD = ischemic heart disease; LAD = left anterior descending coronary artery; MI = myocardial infarction; PCI = percutaneous coronary intervention; TIMI = Thrombolysis In Myocardial Infarction.

intervention electrocardiograms (ECG) were analyzed as a single group by one trained cardiologist blinded to procedural and clinical data. Single-lead ST-segment resolution (STR) was measured by comparing the most prominent ST-segment deviation before coronary angiography and after the procedure according to Schroder et al. (4). After the procedure, patients underwent repeated sampling (every 8 h for 2 days, then every day) for creatine kinase-MB mass assessment.

Angiographic analyses. Coronary angiograms were obtained with the aim of allowing angiographic analyses and were reviewed off-line by two expert interventional cardiologists. Anterograde coronary flow was graded using the standard Thrombolysis In Myocardial Infarction (TIMI) criteria (5). Corrected TIMI frame count (CTFC) was measured according to Gibson et al. (6). Thrombus score was graded as previously described by the TIMI Study Group (7). Myocardial blush grade (MBG) at the end of the procedure was evaluated according to van't Hof et al. (8).

Study end points. The primary end points of the study were the comparison of MBG ≥2 and ST-segment resolution (STR) ≥70% rates between patients randomized to standard PCI and those randomized to manual thrombus-aspiration. In post-hoc analysis, a combination of both primary study end points (MBG ≥2 and STR ≥70%) was used to compare the rate of patients with optimal reperfusion.

Pre-specified secondary end points were the comparison between the two study groups of peak creatine kinase-MB, direct stenting rate, distal embolization rate (abrupt "cut-off" occlusion of a distal branch), and a composite angiographic end point of distal embolization, slow-flow (TIMI flow grade 2), no-reflow (TIMI flow grade 0 to 1).

Statistical analysis. The study sample size was powered to demonstrate a significant difference in the primary end point of rate of STR ≥70%, which was 30% in our registry of primary or rescue PCI without thrombus aspiration, and 60% in the Diver CE (Invatec) pilot study, where thrombus aspiration was employed systematically (1). Starting from such figures and thus assuming a 30% event rate in the control group with an absolute 30% (100% relative) increase in the experimental group, we calculated that 96 patients (48 per group) had to be enrolled to have an alpha error of 0.05 and a power of 0.80 in a prospective 1:1 randomized study. All analyses were planned and conducted according to the intention-to-treat principle, as this approach minimizes the risk of selection bias and alpha error.

Continuous variables (presented as mean ± standard deviation) were compared by the Student *t* test for normally distributed variables and by the Wilcoxon test for non-normally distributed variables. Chi-square tests (Fisher-corrected when at least one cell in a 2 × 2 table had an expected value <5) were used to compare discrete variables (reported as raw numbers [%]). Odds ratios (OR) with 95% confidence intervals (CI) were calculated to compare event rates in the thrombus-aspiration group versus those observed in the standard PCI group (considered as the control group).

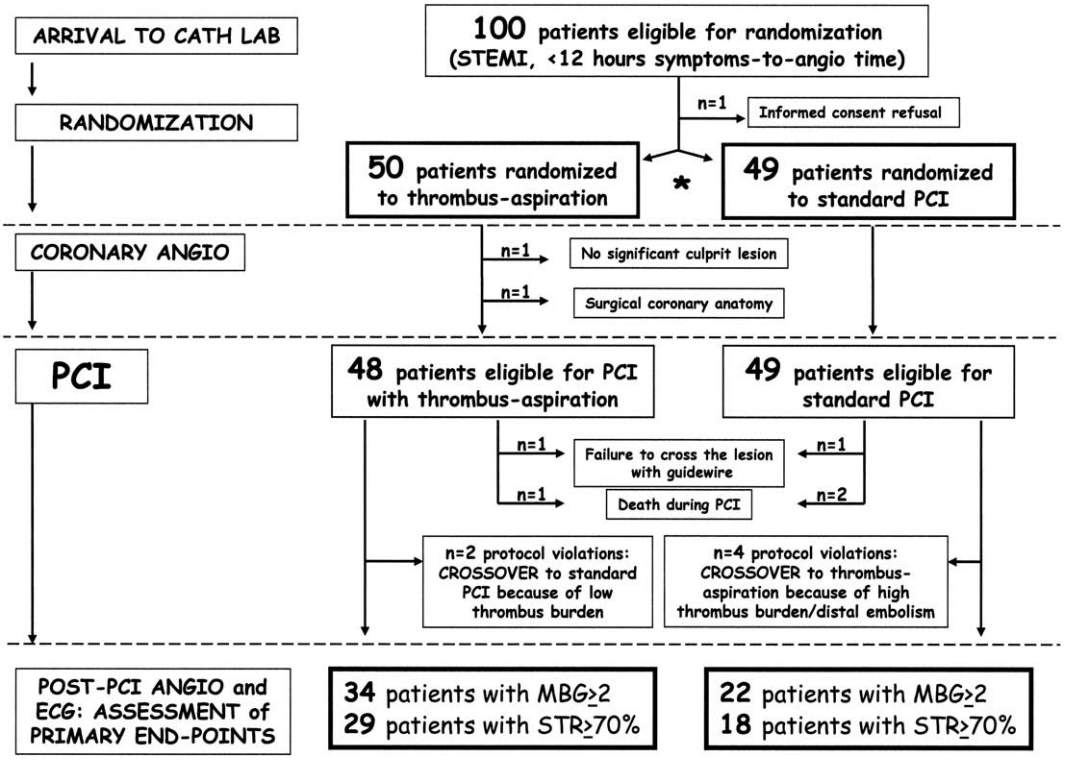

Figure 1. Study flowchart. *Patients entering the intention-to-treat analysis. ECG = electrocardiogram; MBG = myocardial blush grade; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation acute myocardial infarction; STR = ST-segment resolution.

Table 2. Procedural Characteristics

	Thrombus-Aspiration (n = 48*)	Standard PCI (n = 49)	p Value
Angiographic success (%)†	46 (95.8%)	45 (91.8%)	0.67
Procedure time (min)‡	81 ± 43	72 ± 34	0.41
Number of stent per lesion	1.3 ± 0.6	1.3 ± 0.6	0.82
Total stent length	27.2 ± 13.5	26.0 ± 9.7	0.65
Post-dilation	11 (22.9%)	10 (20.4%)	0.76
Maximal balloon inflation pressure (atm)	13.6 ± 1.9	13.6 ± 1.9	0.80
Need of IABP	3 (6.3%)	2 (4.1%)	0.68
Need of pacing	4 (8.3%)	2 (4.1%)	0.44
Treatment of a non-culprit vessel during the same procedure	1 (2.1%)	2 (4.1%)	0.51
CTFC			
Pre-intervention	78 ± 22	80 ± 28	0.50
Post-intervention	23 ± 14	26 ± 19	0.30
Post-intervention value ≤21 (%)	33 (68.8%)	25 (51.0%)	0.07
No reflow	4 (8.3%)	6 (12.2%)	0.74
Slow flow	7 (14.6%)	12 (24.5%)	0.21

*One patient with absence of significant lesion and one with surgical anatomy did not undergo an attempt of PCI. †Angiographic success: residual visual stenosis after stent implantation ≤20%. ‡Procedural time: time from guiding catheter placement to last angiographic view.
CTFC = corrected TIMI frame count; IABP = intra-aortic balloon pump; PCI = percutaneous coronary intervention.

A backward stepwise multivariable logistic regression analysis including the baseline clinical (age, gender, risk factors, history of ischemic heart disease, pre-infarction angina, symptom-to-angiography time, referral for rescue PCI, abcximab administration, cardiogenic shock) and angiographic (culprit vessel, pre-intervention TIMI flow grade, and thrombus score) variables, was also used to further assess and confirm the independent predictive value of randomization to thrombus-aspiration for the achievement of the combination of MBG ≥2 and STR ≥70% (cut-off for entry 0.05, cut-off for removal 0.10). Analyses were carried out using SPSS for Windows 11.0 (SPSS Inc., Chicago, Illinois). Statistical significance was defined by two-tailed $p < 0.05$.

RESULTS

One hundred consecutive patients were screened for the study. One patient refused to give informed consent and was thus excluded from the study, whereas the remaining 99 patients entered the intention-to-treat analysis. As shown in Table 1, the two groups did not differ for any of the baseline clinical or angiographic characteristics.

The study flowchart is represented in Figure 1. Patients who died during the procedure and had non-crossable target lesions were considered to have no reperfusion in the analyses. Data of the patients whose treatment crossed over (4.0% in the thrombus-aspiration group and 8.2% in the standard PCI group) were included in the assigned groups and thus analyzed according to the intention-to-treat principle.

Procedural outcome and angiographic results. One failure to advance the device across the culprit lesion was observed (device failure rate: 1 of 48 attempts, 2.1%). Post–thrombus-aspiration angiography showed a highly significant reduction in the culprit artery's thrombus burden: thrombus score 3.3 ± 1.0 pre–thrombus-aspiration versus 2.3 ± 1.0 after thrombus-aspiration ($p = 0.001$ with Wilcoxon test). Accordingly, thrombus-aspiration significantly improved TIMI flow: TIMI 1.0 ± 1.0 after guidewire crossing and pre–thrombus-aspiration versus 2.0 ± 0.8 post–thrombus-aspiration ($p = 0.001$ with Wilcoxon test). None of the key procedural characteristics were significantly different between the two study groups (Table 2).

Primary end points of the study: rates of MBG ≥2 and STR ≥70%. The rate of MBG ≥2 at the end of the PCI was 68.0% (34 of 50 patients) in the thrombus-aspiration group and 44.9% (22 of 49 patients) in the standard PCI group: odds ratio (OR) 2.6 (95% confidence interval [CI] 1.2 to 5.9), $p = 0.020$ using the chi-square test. The rate of post-PCI STR ≥70% was 58.0% (29 of 46 patients) in the thrombus-aspiration group and 36.7% (18 of 49 patients) in the standard PCI group: OR 2.4 (95% CI 1.1 to 5.3), $p = 0.034$ using the chi-square test.

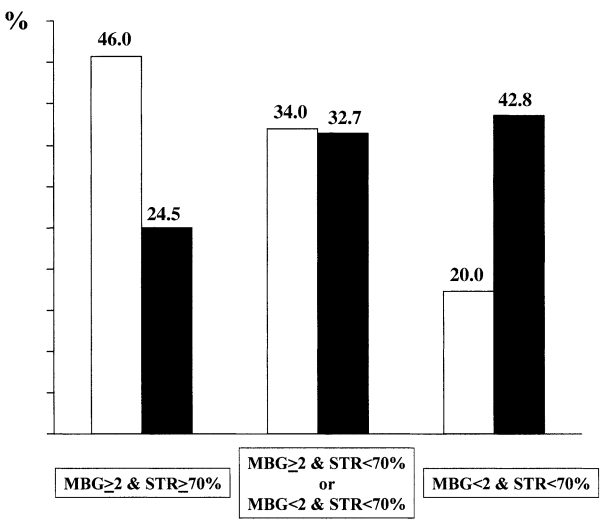

Figure 2. Distribution of patients according to the combination of myocardial blush grade (MBG) ≥2 and ST-segment resolution (STR) ≥70% in the thrombus-aspiration group **(white bars)** and the standard percutaneous coronary intervention group **(black bars)** ($p = 0.025$ using chi-square test).

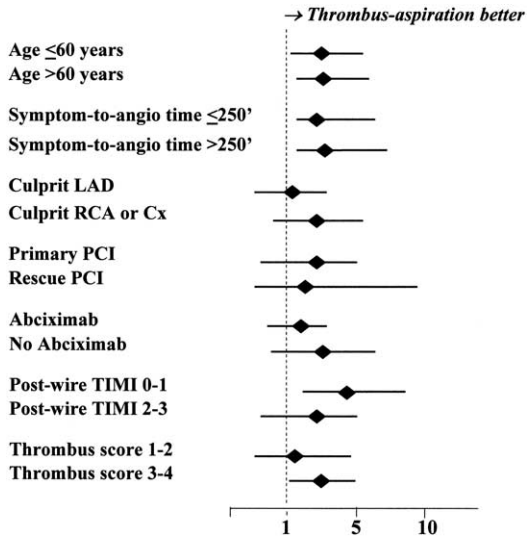

Figure 3. Odds ratios and 95% confidence intervals for the combination of myocardial blush grade ≥2 and ST-segment resolution ≥70% in the comparison between thrombus-aspiration and standard percutaneous coronary intervention (PCI) according to key baseline clinical and angiographic variables. Cx = circumflex artery; LAD = left anterior descending artery; RCA = right coronary artery; TIMI = Thrombolysis In Myocardial Infarction.

The rate of patients with MBG ≥2 and STR ≥70% was significantly greater in the thrombus-aspiration group compared with the standard PCI group: 46.0% (23 of 50 patients) versus 24.5% (12 of 49 patients): OR 2.6 (95% CI 1.1 to 6.2), p = 0.025 using the chi-square test (Fig. 2).

In the multivariate analysis, including the baseline clinical and angiographic parameters, the only independent predictors of the combination of MBG ≥2 and STR ≥70% were a culprit vessel different from the left anterior descending artery (p = 0.010), randomization to thrombus-aspiration (p = 0.013) and primary (vs. rescue) PCI (p = 0.08).

Figure 3 represents the subgroups' ORs for the combination of MBG ≥2 and STR ≥70% in the comparison between the thrombus-aspiration and standard PCI arms according to key baseline clinical and angiographic characteristics. A lower post-guidewire flow and higher thrombus score identified the patients with the greatest combined angiographic and electrocardiographic reperfusion benefit from thrombus-aspiration (Fig. 3).

Secondary end points and in-hospital clinical course. As shown in Table 3, the rate of direct stenting was significantly higher in the thrombus-aspiration arm versus the standard PCI arm (OR 6.0, 95% CI 2.5 to 14.4) and all the key angiographic adverse events tended to occur more commonly in the standard PCI group. Thirty-day major adverse events occurred in 10 patients (10.4%) and did not differ between the two study groups (Table 4).

Table 4. Thirty-Day Major Adverse Events

	Thrombus-Aspiration (n = 48)	Standard PCI (n = 48)
Death		
In the cath lab	1 (2.0%)	2 (4.1%)
After PCI	2 (4.0%)	1 (2.1%)
Reinfarction	2 (4.0%)	2 (4.1%)
Stroke	1 (2.0%)	1 (2.1%)
Target lesion revascularization	1 (2.0%)	1 (2.1%)
Any major adverse event	5 (10.0%)	5 (10.2%)

PCI = percutaneous coronary intervention.

DISCUSSION

The results of the present randomized study show that manual thrombus-aspiration is feasible in unselected patients with STEMI and improves angiographic and ECG myocardial reperfusion. Indeed, the rate of patients with MBG ≥2 increased by 23%, and the rate of patients achieving STR ≥70% increased by 21% with thrombus-aspiration compared to standard PCI.

These data are comparable with the results reported by Napodano et al. (9) and by Antoniucci et al. (10) using more complex devices, but they differ significantly from the more recent data coming from larger multicenter trials. In particular, the Enhanced Myocardial Efficacy and Recovery by Aspiration of Liberated Debris (EMERALD) trial (11) showed that retrieval of embolic debris with the Percusurge Guardwire (Medtronic Corp., Santa Rosa, California) (a distal balloon occlusion and aspiration system) did not result in improvement of myocardial reperfusion and reduced infarct size. Differences in both the devices and the populations studied could explain such divergences. Indeed, although distal occlusive protection implies the abolition of coronary flow until completion of PCI, thrombus-aspiration usually induces (possibly with low risk of distal embolization) an improvement of anterograde flow in the very early phases of PCI. Conversely, there is the possibility that the study population selection may modulate the benefit induced by thrombus removal, the probability to show an

Table 3. Secondary End Points

	Thrombus-Aspiration (n = 50)	Standard PCI (n = 49)	p Value
Direct stenting	33 (66.0%)	12 (24.4%)	0.0001
Distal embolization	4 (8.0%)*	8 (17.8%)	0.19
Composite angiographic end-point (distal embolization, slow flow, or no reflow)	11 (22.0%)	17 (34.7%)	0.16
Peak of CK-MB mass (ng/ml)	256 ± 171	283 ± 158	0.47

*Two cases of distal embolization after thrombus-aspiration and two after stent implantation.
CK-MB = creatine kinase-MB; PCI = percutaneous coronary intervention.

Table 5. Key Characteristics of the Study Populations Enrolled in the Published Randomized Trials Comparing Different Anti-Embolic Devices With Standard PCI

Study	Device	n	Angio Exclusion Criteria	Mean Symptom-to-Balloon Time (min)	Diabetes (%)	Rescue PCI (%)	LAD (%)	TIMI Flow Grade 0–1 (%)	Shock (%)
X-AMINE ST*	X-Sizer	201	RVD <2.5 mm, TIMI ≥2	257	**21**	0	NA	**100**	0
EMERALD (11)	Percusurge Guardwire	**501**	RVD <2.5 mm, ≥30 mm of distal vessel available, No excessive tortuosities or calcifications	250	12	18	39	44	0
Napodano et al. (9)	X-Sizer	92	RVD <2.5 mm	221	13	0	41	NA	0
Antoniucci et al. (10)	Angiojet	100	RVD <2.5 mm	249	17	0	40	NA	**9**
REMEDIA	Diver CE	99	none	**280**†	20	**28**	**47**	88	**9**

The highest number for each column is highlighted in **bold**. *Data obtained from "expert slide presentations" section of the website www.tctmd.com. †Symptom-to-angiography time.

NA = not available; RVD = reference vessel diameter; other abbreviations as in Table 1.

improvement being greater when the risk of no-reflow is higher. In keeping with this hypothesis, as shown in Table 5, the Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus-Aspiration in Primary and Rescue Angioplasty (REMEDIA) study population (as expected by an unselected consecutive series of patients) is characterized by a baseline pattern of adverse predictors of reperfusion, which seems to be worse than that observed in the larger multicenter studies.

Culprit lesions with higher thrombus burden and flow impairment have preliminarily been shown to be associated with a greater device-induced thrombus score reduction and flow improvement (1). Accordingly, in the present study, subgroup analysis showed that patients with lower TIMI flow grade and those with higher thrombus burden might have a greater benefit from thrombus-aspiration. Unfortunately, no systematic quantification of the aspirated material was planned, thus limiting the efficacy estimation of the device to the analysis of the angiographic results. Regarding the composition of the aspirated material, very early data on a subset of these patients suggest that lower fibrin levels are associated with better myocardial reperfusion (12).

Another interesting issue emerging from our study is related to the possible limitations of this technique: despite the positive results obtained, the combination of MBG ≥2 and STR ≥70% was not obtained in more than 50% of the patients randomized to thrombus-aspiration, and distal embolization, slow-flow, or no-reflow occurred in about 20% of them. These figures leave room for further improvements by means, for instance, of adjunct pharmacology or non-occlusive distal protection devices.

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